Site Suitability Template

- This form may be used by Sponsors of clinical trials as part of the application dossier. This is not a mandatory form and different national arrangements may be in place which should be confirmed prior to submission.
- To minimise the number of Request For Information (RFIs) that could be raised during the process and possible rejection, kindly provide detailed and informative responses to each and every question at the best of your knowledge.
- When completing this form, any national guidelines should also be referred to with regards to which sections must be completed. Where no national guidelines exist, the form should be completed in full.
- Where information which is requested in this form is provided elsewhere in the application dossier, the document can just be referenced rather than repeating the information.
- A separate document should be completed and submitted for each site.
- By using this template, the CTR Annex I requirement N.67. is fulfilled.

This template has been endorsed by the EU Clinical Trials Coordination and Advisory Group to comply with Regulation (EU) No. 536/2014 Clinical Trials on Medicinal Products for Human Use.

Section 1	
EU trial number	2023-503692-24-00
Title of clinical trial	A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Study to Evaluate the Efficacy and Safety of Anifrolumab in Adults with Chronic and/or Subacute Cutaneous Lupus Erythematosus who are Refractory and/or Intolerant to Antimalarial Therapy
Name of site, city	SOS Dermatologia Speciale Medica, P.O. Piero Palagi- Azienda - USL Toscana Centro, Viale Michelangiolo, 41 – 50125, Firenze - Italy
If applicable[1], unique identification number of the site	not applicable
Name of principal investigator	Prof. Emiliano Antiga
Planned number of trial participants at the site	2

[1] This request is only applicable in those countries where sites are identified with a unique identification number. This helps identifying the specific site.

Section 2

a) Please provide a comprehensive written statement on the suitability of the site adapted to the nature and use of the investigational medicinal product.

It is hereby stated, that based on the nature and use of the investigational medicinal product, that the human resources, equipment, and facilities are of such quality and adequacy as to conduct the clinical trial undertaken at this trial site as required by ICH-GCP. The site also has the required patient population in which the IMP will be trialled.

Anifrolumab and placebo will be supplied as solutions for SC injection in an accessorized prefilled syringe for either Stage 1 or Stage 2 of the study.

IMPs will be stored as specified by the sponsor (stored between 2°C to 8°C and must not be frozen) and in accordance with applicable regulatory requirements and in accordance with the approved protocol.

In addition to the SOS Dermatologia Speciale Medica, the following facilities (which have the necessary tools to carry out the study) will be involved for both Stage 1 or Stage 2 of the study:

- SOS Farmacia Ospedaliera Firenze II – Santa Maria Nuova (IMPs reception, qualitative-quantitative control of the shipment, registration and transport to the Site)
- Laboratorio di Immunologia Cutanea c/O Ospedale Palagi (samples management for central laboratory shipment and local if required)
- SOS Cardiologia Santa Maria Nuova e Palagi (ECG to be performed locally)
- SOS Radiologia Santa Maria Nuova e Palagi (Chest x-ray management to be performed locally if required)

b) Please describe in detail the suitability of the facilities

The site has acquired significant experience in conducting studies clinical studies by participating as Coordinating Site/Satellite site in several clinical studies and is equipped with the following facilities:

- Physical examination room;
- Facility/Room to collect biologic samples;
- Restricted and secure area to store IMP and to store study documents (ISF, PSF);
- Storage Room for ancillary supply (sharps container, cooler bags and cooler packs)
- Restricted area for dedicated team to train participants on the proper administration technique for anifrolumab or placebo;
- Access to a computer and internet connection, compatible with EDC, IRT and Remote/TeleHealth system;
- Adequate space to receive monitoring visits.

c) Please describe accurately the suitability of the equipment

- Body size measuring device;
- Emergency equipment (e.g.: crash car, emergency medication)
- 12-Lead Electrocardiogram (ECG) machine;
- Thermometers for body temperature (axillary, oral, or tympanic), digital or analogic;

- Access to X-Ray/CT scan facilities;
- Access to pap smear or HPV testing;
- Access to skin biopsy laboratory (if central lab will not be used) and pathologist review for sample interpretation and report (if central lab will not be used);
- Centrifuge (regular and/or refrigerated);
- Freezer (-20°C, -70°C or -80°C) with calibrated thermometer to monitor temperature;
- Refrigerator 2°C – 8°C, with restricted access to study team;
- Thermometer to monitor refrigerator temperature (Max/Min or continuous monitoring);

All equipment is calibrated according to local rules and evidence of calibration is available at site for monitoring, audits and inspections.

In addition the sponsor will provide the following equipment, certified according to current regulations, on loan for use:
- Smartphone for diary and patient questionnaires completion
- Weight scale for body weight;
- Incubator 37°C
- Standard pulse and blood pressure measurement device

d) Please provide a detailed description of all trial procedures which will take place at the site.

All trial procedures will be performed at different timing (Screening, Double-blind Treatment, Open-label Treatment, Follow-up) for either Stage.
All these trial procedures will be conducted at the site for both Stage 1 or Stage 2 of the study:

- Sign informed consent(s);
- Demographical information and general health;
- Physical examination, including height and weight measurement;
- Vital signs measurement;
- Electrocardiogram recording;
- For some female participants, cervical cancer screening (pap smear or human papillomavirus test) if participants do not have suitable results already available from routine screening;
- Chest scans - Chest X-ray or Chest CT (for participants who have not had a chest X-ray or chest CT within 12 weeks prior to signing the ICF) for tuberculosis evaluation;
- Blood and/or urine collection for:
    - Routine safety tests to assess participant's overall health;
    - Tests to determine how healthy the participant's heart and blood vessels are;
    - Immunogenicity;
    - Pharmacokinetics;
    - Pharmacodynamics;
    - Interferon-4 tests;
    - Biomarker assessment;
    - Blood test for TB (IGRA using QFT GIT);
    - Hepatitis B and C serology;
    - HIV test;
    - Serum/urine pregnancy test;
    - Fasting lipid profile for cardiovascular risk assessment;
    - Optional blood sample for DNA insolation (from participants who have consented to participate in the optional genomic analysis component of the study);
- COVID-19 testing;

- Assessment of participant's overall disease severity and health status;
- Skin photography (at least twice during the study) to assess cutaneous lupus activity;
- Questionnaires to be completed by the study team at site: CLASI, CLA-IGA-R, CGIS, CGIC, C-SSRS, COVID-19 questionnaire, TB questionnaire;
- Questionnaires to be completed by the participants (via handheld device) if not completed prior to the site visit: Skindex 29+3, PGIS, PGIC, E5-5D-5L, Medical resource use questionnaire, IP Diary and Injection site reaction Diary, optional interview;
- Study drug or placebo administration and training on how to administer the study drug and placebo;
- A 2 mm punch skin biopsy to be collected during the screening period if the participant does not have an available historical biopsy;Optional lesional 3 mm skin punch biopsy (from a subset of participants who have consented to participate in the optional exploratory biomarker research component of the study);

e) Please provide a <u>detailed</u> description of Human Resources arrangements and expertise at the site

The staff of the site that is and will be involved in the study, delegated and under the supervision of the Principal Investigator, is adequate and qualified to conduct the study for education, training and experience, in accordance with the requirements of the Protocol and current regulations.

The study will involve the following figures:

- Principal Investigator
- Nr. 2 Blinded Sub-Investigators
- Nr. 2 Unblinded Sub-Investigators
- Nr. 1 Blinded Study Coordinator
- Nr. 1 Unblinded Study Nurse
- Nr. 1 Unblided pharmacist
- Nr. 1 Cardiologist
- Nr. 1 Radiologist

Section 3

In authorising this document, I confirm that the site has the facilities and equipment to be able to conduct the clinical trial and has suitable arrangements in place to ensure that all investigators and other individuals involved in conducting the trial have the suitable qualifications, expertise and training in relation to their role in the clinical trial, in compliance with EU Regulation 536/2014, and all conditions identified, which might influence the impartiality of any investigators, were addressed.

ALESSANDRO SERGI
Regione Toscana/01386030488
19.03.2024 08:55:45 GMT+00:00

Issued by:

Name: Dr. Alessandro Sergi

Position: Director Staff Direzione Sanitaria – Azienda USL Toscana
On behalf of the site/organisation

Date: Click here to enter a date.

Please ensure that you have consulted with any national guidelines before submitting this form

NB : The CTR does not require signing individual documents in the clinical trial application – a request for signature could however be subject to national legislation.